

II. REMARKS/ARGUMENTS

A. Summary of the Amendments

The application now contains 27 claims.

Claim 25 has been amended in order to better define the subject matter being claimed.

Claim 31 has been amended in order to correct a minor typographical error identified by the Examiner. Claim 31 has further been amended for clarity, which finds support, for example, in paragraph [0017] of the application.

Claim 33 has been amended to correct minor typographical errors ("polyethylene") and to remove the duplication of certain terms.

New claims 45-51 have been added, which find support, for example, in paragraphs [0058] (claim 45) and [0057] (claims 46-48) and in the Examples (claims 49-51) of the application.

No new matter has been added by way of these amendments.

Claims 26-30 and 32-44 remain the same.

B. Summary of Rejection and Reply

B.1. GENERAL

In the Office Action, the Examiner has objected to claim 31 for being dependent on a cancelled claim.

The Applicant respectfully submits that claim 31 has been amended so as to correct this minor informality. Claim 31 is now dependent on independent claim 25.

B.2. REJECTIONS UNDER 35 USC §103

Claims 25-31, 33-38, 43 and 44

In the Office Action, the Examiner has rejected claims 25-31, 33-38, 43 and 44 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,613,982 (hereafter referred to as Goldstein) in view of U.S. Patent 5,067,962 (hereafter referred to as Campbell) and U.S. Patent 6,146,882 (hereafter referred to as Uematsu).

For the reasons presented below, Applicants respectfully disagree with the Examiner's rejection of claims 25-31, 33-38, 43 and 44, on the basis that the Examiner has failed to establish a *prima facie* case of obviousness.

Firstly, the Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness on the basis that the Uematsu reference relates to the non-analogous field of thermal cycling apparatuses. Uematsu relates to a device comprising a plurality of racks designed to hold a plurality of e.g. nucleic acid samples. The focus of this device is to enable rapid and controlled temperature changes simultaneously for a plurality of samples, so that the samples may be switched rapidly from one temperature to another in an automated fashion. Uematsu thus relates to a device largely intended for the large scale handling of samples (typically tens-hundreds of tubes each containing a small volume of sample) and their processing via controlled, rapid temperature changes, such as the thermal cycling of DNA samples under the polymerase

chain reaction (PCR) method. Such technology has been developed to provide an automated device to handle many samples on a large scale, and effect rapid, controlled changes in temperature of the samples. As noted in Uematsu (col 2, lines 9-10), "it is an object of the invention to provide an incubator which permits high-speed temperature control".

In contrast, the technology of the instant application is in the field of tissue engineering, which in no way relates to the field of large scale, automated/robotic thermal cycling devices. As such, an inventor seeking to solve a problem in the field of tissue engineering would not reasonably be expected to look to the field of thermal cycling devices, in which the Examiner found the Uematsu reference, to find a solution to his or her problem. As per *In re Oetiker* 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed Cir. 1992) "the combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness." Accordingly, since the reference cited by the Examiner relates to non-analogous art, the Applicant respectfully submits that as per *In re Oetiker*, the Examiner has failed to establish a *prima facie* case of obviousness.

In further response to the Examiner's objection, Applicants respectfully direct the Examiner's attention to part (a) of claim 25 as presently amended:

A method of preparing an implant for connective tissue substitution in an animal, said method comprising the steps of:

- a) **providing a pair of bone anchors joined at their proximal ends by at least one support filament, said bone anchors having been joined with said support filament *ex vivo*;**
- b) incubating said pair of bone anchors in a solution containing matrix forming molecules for a period of time sufficient for the formation of at least one matrix layer around said support filament,

wherein said matrix layer has a thickness sufficient to allow for colonization by cells, and wherein said incubation is performed under conditions in which are induced waves, vibrations, cyclic tractions, and/or static tractions of said implant.

Applicants respectfully submit that none of the references cited by the Examiner disclose, teach or suggest the subject matter recited in part (a) of claim 25 as amended. More specifically, neither Goldstein, Campbell or Uematsu describe a method of preparing an implant for connective tissue substitution in an animal, the method comprising providing a pair of bone anchors joined at their proximal ends by at least one support filament, the bone anchors having been joined with the support filament *ex vivo*.

In contrast to claim 25 as amended, Goldstein describes a method of preparing transplant tissue that involves decellularizing a natural tissue (i.e. an *in vivo* prepared base structure) to produce a decellularized tissue matrix, and incubating that matrix in fibroblast cells in order to repopulate the matrix. The implant described by Campbell includes a bone-ligament-bone structure that is harvested directly from a donor animal, and as such this structure is prepared *in vivo*. As noted above, Uematsu is in a non-analogous field and does not relate in any way to implants or methods of preparation thereof. Since neither Goldstein, Campbell nor Uematsu disclose a pair of bone anchors joined by a support filament, the bone anchors having been joined with the support filament *ex vivo*, these references cannot satisfy part (a) of amended claim 25 emphasized above.

Secondly, Campbell further describes that the purpose of their implant is to "preserve intact a substantial portion of a first natural ligament-to-bone attachment structure of the donor animal" (lines 5-6 of the Abstract). As such, Applicants respectfully submit that not only does Campbell not teach the subject matter recited in part (a) of amended claim 25, but that Campbell et al. actually teaches away from the method of preparing an implant as recited in the instant claims as amended.

The Examiner's attention is directed to MPEP §2142, which indicates that "to establish a *prima facie* case of obviousness...the prior art reference (or references when combined) must teach or suggest all the claim limitations." Since neither Goldstein, Campbell nor Uematsu disclose, teach or suggest teach the subject matter recited in part (a) of amended claim 25, Applicants respectfully submit that these references taken either individually or in combination, do not satisfy the requirements to establish a *prima facie* case of obviousness.

In light of the above, Applicants respectfully submit that the requirements to establish a *prima facie* case of obviousness against independent claim 25 as amended, as well as dependent claims 26-31, 33-38, 43 and 44 which incorporate by reference all the limitations of claim 25, cannot be satisfied, and as such the Examiner is respectfully requested to withdraw her rejection of claims 25-31, 33-38, 43 and 44.

Claims 32 and 39-42

In the Office Action, the Examiner has further rejected claims 32 and 39-42 under 35 U.S.C. §103(a) as being unpatentable over Goldstein in view of Campbell et al. and Uematsu et al., in further view of U.S. Patent 6,287,340 (hereafter referred to as Altman).

Applicants respectfully disagree with the Examiner's rejection for the following reasons.

As argued above, since Uematsu relates to a non-analogous art, its combination with other references is insufficient to establish a *prima facie* case of obviousness, consistent with the principles set forth in *In re Oetiker*.

Further, as mentioned above, in order to establish a *prima facie* case of obviousness, the combination of references cited by the Examiner must teach all the limitations found in the claim.

As noted above, neither Goldstein, Campbell nor Uematsu disclose, teach or suggest the subject matter recited in part (a) of amended claim 25, from which claims 32 and 39-42 depend.

Applicants further wish to note that Altman also does not mention nor suggest a "support filament" as recited in the instant claims. Further, Altman et al. does not disclose a pair of bone anchors joined by a support filament, as recited in the instant claims.

Applicants therefore respectfully further submit that Altman also does not disclose, teach or suggest the subject matter recited in part (a) of amended claim 25, as it does not in any way disclose a method of preparing an implant comprising providing a pair of bone anchors joined by a support filament as instantly claimed.

Since Goldstein, Campbell, Uematsu et al. and Altman fail to teach the subject matter of part (a) of independent claim 25 as amended, and since claims 32 and 39-42 are dependent on claim 25, and incorporate by reference all the limitations contained therein, the combination of these references does not meet the requirements to establish a *prima facie* case of obviousness, since not all the limitations found in the independent claim are taught.

In light of the above, Applicants respectfully request that the Examiner withdraw her rejection of claims 32 and 39-44.

CONCLUSION

It is respectfully submitted that claims 25-51 are in condition for allowance. Reconsideration of the rejections and objections is requested. Allowance of claims 25-51 at an early date is solicited.

It is believed this responds to all of the Examiner's concerns, however if the Examiner has any further questions, she is invited to contact the undersigned at (514) 954-1500. Further, If the Examiner does not consider that the application is in a form for allowance, an interview with the Examiner is respectfully requested.

Respectfully submitted,
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